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510(k) SUMMARY

AUG - 3 2006

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Susan Motzer
Date Prepared:	July 12, 2006

B. Trade Name: 1.9F Vascu-PICC™

Common Name: Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days

Classification: LJS

C.F.R. Section: 880.5970

C. Predicate Device: K993052 Vygon 2F Epicutaneo PUR Catheter

D. Device Description:

The Medcomp 1.9F Vascu-PICC™ catheter is designed for peripheral vein catheterization. The 1.9F Vascu-PICC™is comprised of a polyurethane material. The lumen is connected to the extensions by a hub with a suture wing for placement. A clamp is provided on the extension tube to prevent air/fluid communication. A female luer connector provides the connection for intravenous administration. The twisted wire stylet is made of stainless steel with a nylon and high density polyethylene handle. The stylet aids in insertion of the catheter.

E. Intended Use:

The 1.9F Vascu-PICC™ is a long term catheter intended for central venous access via peripheral insertion in neonates, infants, and children. It may be used for administration of fluids, medication, and nutritional therapy.

F. Comparison to Predicate Device:

The Medcomp 1.9F Vascu-PICC™ is substantially equivalent to the Vygon 2F Epicutaneo Catheter in terms of intended use, insertion method, anatomical location, performance and method of sterilization.

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G. Performance Data:

In vitro testing was performed on the Medcomp 1.9F Vascu-PICC™ to assure reliable design and performance in accordance with ISO 10555-1 and 10555-3. Testing includes gravity flow, air leakage, liquid leakage, tensile strength, elongation, air priming volume.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

Biocompatibility testing on the same materials that are included in the 1.9F Vascu-PICC™ were completed on K974236, Medcomp Duo-Flow Soft Line Catheter and K003682, Medcomp Z Cath. These tests demonstrate that the materials used in the 1.9F Vascu-PICC™ meet the requirements of ISO 10993 for a permanent contact device. Biocompatibility testing on the stainless steel with silicone coating of the stylet was completed by the vendor and is enclosed in this submission. These tests demonstrate that the stylet meets requirements of ISO 10993 for a limited externally communicating device with indirect blood path. The handle of the stylet has no patient contact and therefore biocompatibility testing is unnecessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2006

Ms. Susan Motzer
Regulatory Specialist
Medcomp
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K061986
Trade/Device Name: 1.9F Vasu-PICC™
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 13, 2006
Received: July 13, 2006

Dear Ms. Motzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: 1.9F Vascu-PICC™

Indications for Use:

The 1.9F Vascu-PICC™ is a long term catheter intended for central venous access via peripheral insertion in neonates, infants, and children. It may be used for administration of fluids, medication, and nutritional therapy.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...ision of Anesthesiology, General Hospital,
...ection Control, Dental Devices
510(k) Number: K 061986